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PATENT
Attorney Docket No.: 02307E-
161500US
UC Reference: 2004-070-1

On September 13, 2006
TOWNSEND and TOWNSEND and CREW LLP
By: Karen Karlin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tao Jiang et al.

Application No.: 10/699,562

Filed: October 31, 2003

For: PEPTIDES WHOSE UPTAKE BY
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Confirmation No.: 1597

Examiner: Dameron Levest Jones

Art Unit: 1618

**RESPONSE TO RESTRICTION
REQUIREMENT**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the restriction requirement mailed July 13, 2006, Applicants elect Group 1, claims 1-48 and 51-56, drawn to molecules comprising A-X-B wherein SEQ ID NO:1 (PLGLAG) is utilized. For the purposes of searching, Applicants elect the species SEQ ID NO:13, which comprises portions A, X, B, and C.

A petition to extend the time for response for one month, from August 13, 2006 to September 13, 2006, is submitted herewith.

The foregoing election is made with traverse, as the 15 set forth by the Examiner all stem from a common concept and theory, and are thus related, as described below. Applicants therefore reserve the right to petition this requirement.

The present application contains generic composition claims and claims

directed to methods of use. Of the 54 pending claims, two dependent claims recite a single SEQ ID NO: (claims 41 and 42 recite SEQ ID NOS:1 and 2, respectively). No other sequences are listed in the claims. However, the Examiner has restricted the claims based on these sequences. For example, the same polypeptide composition claims are divided into three groups: SEQ ID NO:1, SEQ ID NO:2, and sequences not SEQ ID NO:1 or SEQ ID NO:2. The methods claims, nucleic acid claims, and fluorescent molecule claims are likewise divided. Applicants submit that the Examiner has improperly restricted individual claims into more than one group, and therefore has refused to examine the claims as drafted. Moreover, although each of the inventions in Groups 1-3, 4-9, and 10-15, respectively, fall in the same class and subclass, the Examiner has stated that searching the claim as drafted would impose an undue burden.

Applicants therefore respectfully request that the Examiner withdraw the Restriction Requirement and consider the claims of Groups 1-3 together, the claims of groups 4-9 together, the claims of groups 10-12 together, and the claims of groups 13-15 together.

Restricting a single claim into more than one group is improper

Each of the composition, method, nucleic acid, and fluorescent molecule claims are divided into three or more groups. It has long been held that an Examiner may not reject a particular claim on the basis that it represents “independent and distinct” inventions. *See, In Re Weber, Soder and Boksay*, 198 USPQ 328, 331 (CCPA 1978) (emphasis added). *See also, In Re Haas*, 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas*, 198 USPQ 334-337 (*In Re Haas II*). The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the CCPA has noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay, Supra.

Instead of improperly imposing a restriction requirement on a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See, 37 C.F.R. § 1.146.* This practice strikes an appropriate balance between the concerns of the Patent Office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §

112 are complied with. *See*, the MPEP at 803.02. *See also*, *In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973).

Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application. It should be clear that the added costs of filing and prosecuting 15 patent applications (instead of three applications: (1) peptides and methods of use, (2) nucleic acids, and (3) fluorescent molecules) in the present case do not strike an appropriate balance between the administrative concerns of the Office and Applicants' statutory rights as inventors.

Searching the claims together would not present an undue burden

According to the MPEP, where claims can be examined together without undue burden, the Examiner *must* examine the claims on the merits even though they are directed to independent and distinct inventions. *See*, the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner *must* show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search (MPEP at § 808.02).

In the present restriction, the Examiner has provided only cursory statements as to why Groups 1-3, 4-9, 10-12, and 13-15, respectively, cannot be examined together. For Groups 1-3, the sequences are all listed in the same class and subclass. Similarly, the sequences of Groups 4-9, and 10-15 are listed in the same class and subclass. Although the Examiner admits that the "some" of the inventions classify in the same subclass, "a separate search is required because the sequences present in each of the products is distinct from one another." Office Action, page 4, lines 20-22. This reasoning is cursory and does not explain why the claims should be restricted into groups


classified in the same class and subclass. Applicants suggest that the proper method of searching the claim is to request a species election.

The Examiner has not provided any reasoning to show why examining the claims would lead to a burdensome search of the prior art. The Examiner has provided no reasoning to show that the 15 Groups meet the other two criteria required under §808.02, such as a showing that the groups have a separate classification. Applicants therefore respectfully request that the requirement be withdrawn.

Conclusion

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


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